

FORM PTO-1449/A and B (modified PTO/SB/08)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

APPLICATION NO.: 09/316,199

ATTY. DOCKET NO.: C1040.70006US00

FILING DATE: May 21, 1999

CONFIRMATION NO.: 7506

APPLICANT: McCluskie et al.

GROUP ART UNIT: 1633

EXAMINER: Ileana Popa

Sheet

1

of

10

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		09/167,039		Raz et al.	10-05-1998
		4,627,850		Deters et al.	12-09-1986
		4,806,463		Goodchild et al.	02-21-1989
		5,004,810		Draper	04-02-1991
		5,166,195		Ecker	11-24-1992
		5,194,428		Agrawal et al.	03-16-1993
		5,264,423		Cohen et al.	11-23-1993
		5,276,019		Cohen et al.	01-04-1994
		5,457,189		Crooke et al.	10-10-1995
		5,514,577		Draper et al.	05-07-1996
		5,594,122		Friesen	01-14-1997
		5,684,147		Agrawal et al.	11-04-1997
		5,723,335		Hutcherson et al.	03-03-1998
		5,840,332		Lerner et al.	11-24-1998
		5,877,309		McKay et al.	03-02-1999
		6,184,369	B1	Rando et al.	02-06-2001
		6,210,663	B1	Ertl	04-03-2001
		6,218,371	B1	Krieg et al.	04-17-2001
		6,498,147	B1	Nerenberg et al.	12-24-2002
		6,498,148	B1	Raz	12-24-2002
		6,503,533	B1	Korba et al.	01-07-2003
		6,558,670	B1	Friede et al.	05-06-2003
		6,630,455	B1	Mitchell	10-07-2003
		6,653,292	B1	Krieg et al.	11-25-2003
		6,693,086	B1	Dow et al.	02-17-2004
		6,727,230	B1	Hutcherson et al.	04-27-2004
		6,852,705	B2	Audonnet et al.	02-08-2005
		7,049,302	B1	Kensil	05-23-2006
		2001-0044416	A1	McCluskie et al.	11-22-2001
		2002-0192184	A1	Carpentier et al.	12-19-2002
		2003-0232443	A1	Bennett et al.	12-18-2003

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	2	of	10				

		2004-0157791	A1	Dow et al.	08-12-2004
		2004-0247662	A1	Dow et al.	12-09-2004
		2005-0019340	A1	Garcon et al.	01-27-2005
		2005-0031638	A1	Dalemans et al.	02-10-2005
		2005-0176672	A1	Scheule et al.	08-11-2005
		2005-0209184	A1	Klinman et al.	09-22-2005
		2005-0249794	A1	Semple et al.	11-10-2005
		2006-0223769	A1	Dow et al.	10-05-2006
		2007-0202575	A1	Klinman et al.	08-03-2007

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
		CN	1 468 957		Military Medical Univ	01-21-2004	Y-Abstract
		KR	2001063153		Genexine Inc.	07-09-2001	Y-Abstract
		WO	95/24929	A2	Brown University Research Foundation	09-21-1995	
		WO	96/40162	A1	East Carolina University	12-19-1996	
		WO	97/03702	A1	Brown University Research Foundation	02-06-1997	
		WO	97/26802	A1	Chr. Hansen A/S	07-31-1997	
		WO	98/37919	A1	University of Iowa Research Foundation	09-03-1998	
		WO	98/40100	A1	Ottawa Civic Loeb Research Institute	09-17-1998	
		WO	98/49288	A1	Hybridon Inc.	11-05-1998	
		WO	98/51278	A2	INEX Pharmaceuticals Corp.	11-19-1998	
		WO	99/30686	A1	INEX Pharmaceuticals Corporation	06-24-1999	
		WO	99/33868	A2	SmithKline Beecham Biologicals, S.A.	07-08-1999	
		WO	99/52549	A1	SmithKline Beecham Biologicals S.A.	10-29-1999	
		WO	99/55743	A1	INEX Pharmaceuticals Corporation	11-04-1999	
		WO	99/56755	A1	University of Iowa Research Foundation	11-11-1999	
		WO	00/03683	A2	INEX Pharmaceuticals Corporation	01-27-2000	
		WO	00/15256	A2	Pasteur Merieux Serums Et Vaccins [FR]	03-23-2000	Y-Abstract
		WO	00/41463	A2	SmithKline Beecham Biologicals, S.A.	07-20-2000	
		WO	00/67787	A2	The Immune Response Corporation	11-16-2000	
		WO	01/35991	A2	Dynavax Technologies Corporation	05-25-2001	
		WO	01/45750	A1	Regents of the University of California	06-28-2001	
		WO	01/68144	A2	Dynavax Technologies Corporation	09-20-2001	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	3	of	10				

		WO	02/36767	A3	INEX Pharmaceuticals Corporation	05-10-2002	
		WO	2008/139262	A2	Coley Pharmaceutical GMBH	11-20-2008	

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		Notice of Opposition in EP Application No. 99925754.6 dated May 25, 2007.	
		Response to Opposition in EP Application No. 99925754.6 dated June 24, 2008.	
		Press Release, January 2007, "Coley Pharmaceutical Group Updates Hepatitis C Drug Development Strategy".	
		Press Release, June 2007, "Coley Pharmaceutical Group Announces Pfizer's Discontinuation of Clinical Trials for PF-3512676 Combined with Cytotoxic Chemotherapy in Advanced Non Small Cell Lung Cancer".	
		AGRAWAL et al., Chapter 19: Pharmacokinetics and bioavailability of antisense oligonucleotides following oral and colorectal administrations in experimental animals. 1998: 525-43.	
		ANITESCU et al., Interleukin-10 functions in vitro and in vivo to inhibit bacterial DNA-induced secretion of interleukin-12. J Interferon Cytokine Res. 1997 Dec;17(12):781-8.	
		BENNETT, Intracellular delivery of oligonucleotides with cationic liposomes. In: Delivery Strategies for Antisense Oligonucleotide Therapeutics. Akthar, Ed. 1995:223-32.	
		BRANDA et al., B-cell proliferation and differentiation in common variable immunodeficiency patients produced by an antisense oligomer to the rev gene of HIV-1. Clin Immunol Immunopathol. 1996 May;79(2):115-21.	
		BRAZOLOT MILLAN et al., CpG DNA can induce strong Th1 humoral and cell-mediated immune responses against hepatitis B surface antigen in young mice. Proc Natl Acad Sci U S A. 1998 Dec 22;95(26):15553-8.	
		BROIDE et al., Immunostimulatory DNA sequences inhibit IL-5, eosinophilic inflammation, and airway hyperresponsiveness in mice. J Immunol. 1998 Dec 15;161(12):7054-62.	
		CARPENTIER et al., Oligodeoxynucleotides containing CpG motifs can induce rejection of a neuroblastoma in mice. Cancer Res. 1999 Nov 1;59(21):5429-32.	
		CHO et al., Immunostimulatory DNA-based vaccines induce cytotoxic lymphocyte activity by a T-helper cell-independent mechanism. Nat Biotechnol. 2000 May; 18:509-14.	
		CHU et al., CpG oligodeoxynucleotides down-regulate macrophage class II MHC antigen processing. J Immunol. 1999 Aug 1;163(3):1188-94.	
		COHEN, Selective anti-gene therapy for cancer: principles and prospects. Tohoku J Exp Med. 1992 Oct;168(2):351-9.	
		COOPER et al., Safety and immunogenicity of CPG 7909 injection as an adjuvant to Fluarix influenza vaccine. Vaccine. 2004 Aug 13;22(23-24):3136-43.	
		COOPER et al., CPG 7909 adjuvant improves hepatitis B virus vaccine seroprotection in antiretroviral-treated HIV-infected adults. AIDS. 2005 Sep 23;19(14):1473-9.	
		COSSUM et al., Disposition of the 14C-labeled phosphorothioate oligonucleotide ISIS 2105 after intravenous administration to rats. J Pharmacol Exp Ther. 1993 Dec;267(3):1181-90.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	4	of	10				

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		COWSERT et al., In vitro evaluation of phosphorothioate oligonucleotides targeted to the E2 mRNA of papillomavirus: potential treatment for genital warts. Antimicrob Agents Chemother. 1993 Feb;37(2):171-7.	
		CROOKE et al., Phosphorothioate Oligonucleotides. Therapeut Apps. 1995;ch5:63-84.	
		CRYZ et al., European Commission COST/STD Initiative. Report of the expert panel VII. Vaccine delivery systems. Vaccine. 1996 May;14(7):665-90.	
		DAVILA et al., Repeated administration of cytosine-phosphorothiolated guanine-containing oligonucleotides together with peptide/protein immunization results in enhanced CTL responses with anti-tumor activity. J Immunol. 2000 Jul 1;165(1):539-47.	
		DAVIS et al., Chapter 18:DNA-based immunization. in Molecular and Cell Biology of Human Gene Therapeutics. Dickson, Ed. 1995; p368	
		DAVIS et al., CpG DNA overcomes hyporesponsiveness to hepatitis B vaccine in orangutans. Vaccine. 2000 Mar 17;18(18):1920-4.	
		DAVIS et al., Single-agent monoclonal antibody efficacy in bulky non-Hodgkin's lymphoma: Results of a phase II trial of Rituximab. J. Clin. Oncol. 1999;17:1851-7.	
		DAVIS et al., CpG ODN is safe and highly effective in humans as adjuvant to HBV vaccine: Preliminary results of Phase I trial with CpG ODN 7909. Third Annual Conference on Vaccine Res. 2000. Abstract s25, number 47.	
		DECKER et al., Immunostimulatory CpG-oligonucleotides cause proliferation, cytokine production, and an immunogenic phenotype in chronic lymphocytic leukemia B cells. Blood. 2000 Feb 1;95(3):999-1006.	
		DE LA ROSA et al., Microbiological quality of pharmaceutical raw materials. Pharm Acta Helv. 1995;70:227-232.	
		DIWAN et al., Biodegradable nanoparticle mediated antigen delivery to human cord blood derived dendritic cells for induction of primary T cell responses. J Drug Target. 2003;11(8-10):495-507. Abstract Only.	
		EASTCOTT et al., Oligonucleotide containing CpG motifs enhances immune response to mucosally or systemically administered tetanus toxoid. Vaccine. 2001 Feb 8;19(13-14):1636-42.	
		FIELDS et al., Fields' Virology. 2001;1:1153.	
		FILION et al., Major limitations in the use of cationic liposomes for DNA delivery. Int J Pharmaceut. 1998; 162:159-70.	
		FRALEY et al., New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids. Trends Biochem Sci. 1981;6:77-80.	
		GAO et al., Swelling of hydroxypropyl methylcellulose matrix tablets. 2. Mechanistic study of the influence of formulation variables on matrix performance and drug release. J Pharm Sci. 1996;85:732-740.	
		GEISLER et al., Enhancement of cellular and humoral immune responses to hepatitis C virus core protein using DNA-based vaccines augmented with cytokine-expressing plasmids. J Immunol. 1997 Feb 1;158(3):1231-7.	
		GOMBOTZ et al., Protein release from alginate matrices. Adv Drug Deliv Rev. 1998;31:267-285.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	5	of	10				

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		GREGORIADIS et al., Liposomes for drugs and vaccines. Trends Biotechnol. 1985;3:235-41.	
		HARTMANN et al., Spontaneous and cationic lipid-mediated uptake of antisense oligonucleotides in human monocytes and lymphocytes. J Pharmacol Exp Ther. 1998 May;285(2):920-8.	
		HASLETT et al., Strong human immunodeficiency virus (HIV)-specific CD4+ T cell responses in a cohort of chronically infected patients are associated with interruptions in anti-HIV chemotherapy. J Infect Dis. 2000 Apr;181(4):1264-72. Epub 2000 Apr 05.	
		HAVLIR et al., Maintenance antiretroviral therapies in HIV infected subjects with undetectable plasma HIV RNA after triple-drug therapy. AIDS Clinical Trials Group Study 343 Team. N Engl J Med. 1998 Oct 29;339(18):1261-8.	
		HAYNES et al., Particle-mediated nucleic acid immunization. J Biotechnol. 1996 Jan 26;44(1-3):37-42.	
		HIGAKI et al., Mechanisms involved in the inhibition of growth of a human B lymphoma cell line, B104, by anti-MHC class II antibodies. Immunol Cell Biol. 1994 Jun;72(3):205-14.	
		HINKULA et al., Recognition of prominent viral epitopes induced by immunization with human immunodeficiency virus type 1 regulatory genes. J Virol. 1997 Jul;71(7):5528-39.	
		HO, Toward HIV eradication or remission: the tasks ahead. Science. 1998 Jun 19;280(5371):1866-7.	
		HODES, T-Cell-mediated regulation: help and suppression. in Fundamental Immunology, second edition. Paul, Ed. 1989; pp 587-620.	
		HOLMGREN et al., Cholera toxin and cholera B subunit as oral-mucosal adjuvant and antigen vector systems. Vaccine. 1993 Sep;11(12):1179-84.	
		HORNER et al., Immunostimulatory sequence oligodeoxynucleotide: A novel mucosal adjuvant. Clin Immunol. 2000 Apr;95(1 Pt 2):S19-29.	
		IMAMI et al., Assessment of type 1 and type 2 cytokines in HIV type 1-infected individuals: impact of highly active antiretroviral therapy. AIDS Res Hum Retroviruses. 1999 Nov 20;15(17):1499-508.	
		JACOBSON et al., Early viral response and on treatment response to CpG 10101 (ACTILON™), in combination with pegylated interferon and/or ribavirin, in chronic HCV genotype 1 infected patients with prior relapse response. 57 th Annual Meeting of American Association for the Study of the Liver Diseases (AASLD). 2006 Oct 30, Boston, Massachusetts; Presented Abstract #96.	
		JOHNSON et al., Non-specific resistance against microbial infections induced by polyribonucleotide complexes. In: Immunopharmacology of infection diseases: Vaccine adjuvants and modulators of non-specific resistance. 1987: 291-301.	
		KLINMAN et al., Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection. Infect Immun. 1999 Nov;67(11):5658-63.	
		KNIFE et al., Fields' Virology. 2001;1:1004-16.	
		KNIFE et al., eds., Fields' Virology. 2001;1:1564.	
		KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199	ATTY. DOCKET NO.: C1040.70006US00
				FILING DATE: May 21, 1999	CONFIRMATION NO.: 7506
				APPLICANT: McCluskie et al.	
				GROUP ART UNIT: 1633	EXAMINER: Ileana Popa
Sheet	6	of	10		

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.	
		KRIEG et al., P-chirality-dependent immune activation by phosphorothioate CpG oligodeoxynucleotides. Oligonucleotides. 2003;13(6):491-9.	
		KRIEG et al., Chapter 17:Immune stimulation by oligonucleotides. in Antisense Drug Tech. 2001;1394:471-515.	
		KRIEG et al., How to exclude immunostimulatory and other nonantisense effects of antisense oligonucleotides. Manual of Antisense. 1999:79-89.	
		KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.	
		KRIEG et al., Unmethylated CpG DNA protects mice from lethal listeria monocytogenes challenge. Vaccines. 1997; 97:77-9.	
		KRIEG et al., Infection. In: McGraw Hill Book. 1996:242-3.	
		KRIEG, Therapeutic potential of Toll-like receptor 9 activation. Nat Rev Drug Discov. 2006 Jun;5(6):471-84.	
		KRIEG et al., Induction of systemic TH1-like innate immunity in normal volunteers following subcutaneous but not intravenous administration of CPG 7909, a synthetic B-class CpG oligodeoxynucleotide TLR9 agonist. J Immunother. 2004 Nov-Dec;27(6):460-71.	
		KRIEG et al., Now I know my CpGs.Trends Microbiol. 2001 Jun;9(6):249-52.	
		KRIEG, Signal transduction induced by immunostimulatory CpG DNA. Springer Semin Immunopathol. 2000;22(1-2):97-105.	
		KRIEG et al., Antiinfective applications of toll-like receptor 9 agonists. Proc Am Thorac Soc. 2007 Jul;4(3):289-94.	
		KULKARNI et al., Effect of dietary nucleotides on response to bacterial infections. JPEN J Parenter Enteral Nutr. 1986 Mar-Apr;10(2):169-71.	
		KURAMOTO et al., Oligonucleotide sequences required for natural killer cell activation. Jpn J Cancer Res. 1992 Nov;83(11):1128-31.	
		LEE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. Immunology. 1998 Jul;94(3):285-9.	
		LETSINGER et al., Cholesteryl-conjugated oligonucleotides: synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture. Proc Natl Acad Sci U S A. 1989 Sep;86(17):6553-6.	
		LETSINGER et al., Synthesis and properties of modified oligonucleotides. Nucleic Acids Symp Ser. 1991;(24):75-8.	
		LITZINGER et al., Fate of cationic liposomes and their complex with oligonucleotide in vivo. Biochim Biophys Acta. 1996 Jun 11;1281(2):139-49.	
		LIU et al., Recombinant interleukin-6 protects mice against experimental bacterial infection. Infect Immun. 1992 Oct;60(10):4402-6.	
		LIU et al., CpG ODN is an effective adjuvant in immunization with tumor antigen. J Invest Med. 1997 Sept7;45(7):333A.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	7	of	10				

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		LIU et al., Immunization of non-human primates with DNA vaccines. Vaccine. 1997 Jun;15(8):909-12.	
		LOKE et al., Delivery of c-myc antisense phosphorothioate oligodeoxynucleotides to hematopoietic cells in culture by liposome fusion: specific reduction in c-myc protein expression correlates with inhibition of cell growth and DNA synthesis. Curr Top Microbiol Immunol. 1988;141:282-9.	
		MacFARLANE et al., Unmethylated CpG-containing oligodeoxynucleotides inhibit apoptosis in WEHI 231 B lymphocytes induced by several agents: evidence for blockade of apoptosis at a distal signalling step. Immunology. 1997 Aug;91(4):586-93.	
		MAJOR et al., Chapter 34 Hepatitis C Viruses. in Fields' Virology. 2001; 1:1127-61	
		MALTESE et al., Sequence context of antisense RelA/NF-kappa B phosphorothioates determines specificity. Nucleic Acids Res. 1995 Apr 11;23(7):1146-51.	
		MANEGOLD et al., Addition of PF-3512676 (CpG 7909) to a taxane/platinum regimen for first-line treatment of unresectable non-small cell lung cancer (NSCLC) improves objective response—Phase II clinical trial. Pfizer Poster. 2005. Abstract 1131.	
		MANZEL et al., CpG-oligodeoxynucleotide-resistant variant of WEHI 231 cells. J Leukoc Biol. 1999 Nov;66(5):817-21.	
		MATSUKURA et al., Regulation of viral expression of human immunodeficiency virus in vitro by an antisense phosphorothioate oligodeoxynucleotide against rev (art/trs) in chronically infected cells. Proc Natl Acad Sci U S A. 1989 Jun;86(11):4244-8.	
		McCLUSKIE et al., CpG DNA as mucosal adjuvant. Immunol Letts. 1999;69(1):30-1. Abstract #5.2	
		McCLUSKIE et al., CpG DNA as mucosal adjuvant. Vaccine. 2000;18: 231-7.	
		McCLUSKIE et al., Novel adjuvant systems. Curr Drug Targets Infect Disord. 2001 Nov;1(3):263-71.	
		McCLUSKIE et al., Treatment of intravaginal HSV-2 infection in mice: a comparison of CpG oligodeoxynucleotides and resiquimod (R-848). Antiviral Res. 2006 Feb;69(2):77-85. Epub 2005 Dec 5.	
		McCLUSKIE et al., Enhancement of infectious disease vaccines through TLR9-dependent recognition of CpG DNA. Curr Top Microbiol Immunol. 2006;311:155-78. Abstract Only.	
		McHUTCHISON et al., Early viral response to CpG 10101, in combination with pegylated interferon and/or ribavirin, in chronic HCV genotype 1 infected patients with prior relapse response. 41 st Annual Meeting of European Association for the Study of the Liver (EASL). 2006 April 26-30, Vienna, Austria; Submitted Abstract.	
		McHUTCHISON et al., Final results of a multi-center phase 1B, randomized, placebo-controlled, dose-escalation trial of CpG 10101 in patients with chronic hepatitis C virus. 41 st Annual Meeting of European Association for the Study of the Liver (EASL). 2006 April 30, Vienna, Austria; Presented Abstract #111.	
		McHUTCHISON et al., Early clinical results with CpG 10101, a new investigational antiviral TLR9 agonist being developed for treatment of subjects chronically infected with hepatitis C virus. 12 th International Symposium on Viral Hepatitis and Liver Disease (ISVHLD). 2006 July 3, Paris, France; Presented Abstract #O105.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	8	of	10				

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		OCHIAI et al., Studies on lymphocyte subsets of regional lymph nodes after endoscopic injection of biological response modifiers in gastric cancer patients. Int J Immunotherapy. 1986;11(4):259-65.	
		OEHEN et al., Antiviral protection after DNA vaccination is short lived and not enhanced by CpG DNA. Immunology. 2000 Feb;99(2):163-9.	
		PERLAKY et al., Growth inhibition of human tumor cell lines by antisense oligonucleotides designed to inhibit p120 expression. Anticancer Drug Des. 1993 Feb;8(1):3-14.	
		PISETSKY et al., The influence of base sequence on the immunological properties of defined oligonucleotides. Immunopharmacology. 1998 Nov;40(3):199-208.	
		POLANCZYK et al., Immunostimulatory effects of DNA and CpG motifs. Cent Eur J of Immunol. 2000;25(3):160-6.	
		RATAJCZAK et al., In vivo treatment of human leukemia in a scid mouse model with c-myb antisense oligodeoxynucleotides. Proc Natl Acad Sci U S A. 1992 Dec 15;89(24):11823-7.	
		RAZ et al., Potential role of immunostimulatory DNA sequences (ISS) in genetic immunization and autoimmunity. ACR Poster Session C: Cytokines and Inflammatory Mediators. 1996 Oct 20; Abstract 615.	
		ROBERTSON et al., Crohn's trial shows the pros of antisense. Nat Biotechnol. 1997 Mar;15(3):209.	
		RYNKIEWICZ et al., Marked enhancement of antibody response to anthrax vaccine adsorbed with CPG 7909 in healthy volunteers. 45 th Intersci. Conf. Antimicrob. Agents Chemother. 2005 Sep. 21-24; New Orleans, Louisiana. Meeting Poster.	
		SATOH et al., The study of mechanisms in CpG oligodeoxynucleotides-induced aggravation in murine allergic contact dermatitis to 2,4-dinitrofluorobenzene. Fukushima Igaku Zasshi. 2002;52(3):237-50. Abstract Only.	
		SCHIJNS et al., Immunological concepts of vaccine adjuvant activity. Curr Opin Immunol. 2000;12:456-463.	
		SEDEGAH et al., Interleukin 12 induction of interferon gamma-dependent protection against malaria. Proc Natl Acad Sci U S A. 1994 Oct 25;91(22):10700-2.	
		SHALABY, Development of oral vaccines to stimulate mucosal and systemic immunity: barriers and novel strategies. Clin Immunol Immunopathol. 1995 Feb;74(2):127-34.	
		SIDMAN et al., Gamma-interferon is one of several direct B cell-maturing lymphokines. Nature. 1984 Jun 28-Jul 4;309(5971):801-4.	
		SONEHARA et al., Hexamer palindromic oligonucleotides with 5'-CG-3' motif(s) induce production of interferon. J Interferon Cytokine Res. 1996 Oct;16(10):799-803.	
		SPARWASSER et al., Immunostimulatory CpG-oligodeoxynucleotides cause extramedullary murine hemopoiesis. J Immunol. 1999 Feb 15;162(4):2368-74.	
		STEIN et al., Problems in interpretation of data derived from in vitro and in vivo use of antisense oligodeoxynucleotides. Antisense Res Dev. 1994 Summer;4(2):67-9.	
		STEIN et al., Non-antisense effects of oligodeoxynucleotides. Antisense Technology. 1997; Ch. 11: 241-64.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	9	of	10				

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		SUN et al., DNA as an adjuvant: capacity of insect DNA and synthetic oligodeoxynucleotides to augment T cell responses to specific antigen. J Exp Med. 1998 Apr 6;187(7):1145-50.	
		VAN OJIK et al., Phase I/II study with CpG 7909 as adjuvant to vaccination with MAGE-3 protein in patients with MAGE-3 positive tumors. Ann Oncol. 2003;13:157. Abstract 579O.	
		VLASSOV et al., In Vivo pharmacokinetics of oligonucleotides following administration by different routes. CRC Press, Inc. Chapter 5. 1995:71-83.	
		WAGNER et al., CpG motifs are efficient adjuvants for genetic vaccines to induce antigen-specific protective anti-tumor T cell responses. 2000;203:429. Abstract R46.	
		WEERATNA et al., TLR agonists as vaccine adjuvants: comparison of CpG ODN and Resiquimod (R-848). Vaccine. 2005;23:5263-5270.	
		WEINER, The immunobiology and clinical potential of immunostimulatory CpG oligodeoxynucleotides. J Leukoc Biol. 2000 Oct;68(4):455-63.	
		WEINER et al., Immunostimulatory CpG oligodeoxynucleotide is effective as an adjuvant in inducing production of anti-idiotypic antibody and is synergistic with GMCSF. Blood. 1996 Nov 15;88(10):Suppl. 1 pt. 1. Abstract #348.	
		WHALEN et al., DNA-mediated immunization to the hepatitis B surface antigen. Activation and entrainment of the immune response. Ann N Y Acad Sci. 1995 Nov 27;772:64-76.	
		WHITESSELL et al., Stability, clearance, and disposition of intraventricularly administered oligodeoxynucleotides: implications for therapeutic application within the central nervous system. Proc Natl Acad Sci U S A. 1993 May 15;90(10):4665-9.	
		WHITMORE et al., LPD lipopolyplex initiates a potent cytokine response and inhibits tumor growth. Gene Ther. 1999;6:1867-75.	
		WOOLDRIDGE et al., Select unmethylated CpG oligodeoxynucleotide improve antibody dependent cellular cytotoxicity in vitro and in vivo. Proc Am Assoc Cancer Res. 1996 Mar;37(3253):477. Abstract.	
		WOOLDRIDGE et al., Immunostimulatory oligodeoxynucleotides containing CpG motifs enhance the efficacy of monoclonal antibody therapy of lymphoma. Blood. 1997 Apr 15;89(8):2994-8.	
		YAMAMOTO et al., [Commemorative lecture of receiving Imamura Memorial Prize. II. Mode of action of oligonucleotide fraction extracted from Mycobacterium bovis BCG] Kekkaku. 1994 Sep;69(9):571-4. Japanese.	Yes
		YAMAMOTO et al., Oligodeoxyribonucleotides with 5'-ACGT-3' or 5'-TCGA-3' sequence induce production of interferons. Curr Top Microbiol Immunol. 2000;247:23-39.	
		YAMAMOTO, Cytokine production inducing action of oligo DNA. Rinsho Meneki. 1997; 29(9): 1178-84. Japanese.	Yes
		YEW et al., Contribution of plasmid DNA to inflammation in the lung after administration of cationic lipid:pDNA complexes. Hum Gene Ther. 1999 Jan 20;10:223-34.	
		YI et al., CpG DNA rescue of murine B lymphoma cells from anti-IgM-induced growth arrest and programmed cell death is associated with increased expression of c-myc and bcl-xL. J Immunol. 1996 Dec 1;157(11):4918-25.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 09/316,199		ATTY. DOCKET NO.: C1040.70006US00	
				FILING DATE: May 21, 1999		CONFIRMATION NO.: 7506	
				APPLICANT: McCluskie et al.			
				GROUP ART UNIT: 1633		EXAMINER: Ileana Popa	
Sheet	10	of	10				

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		ZHAO et al., Modulation of oligonucleotide-induced immune stimulation by cyclodextrin analogs. Biochem Pharmacol. 1996 Nov 22;52(10):1537-44.	
		ZIMMERMANN et al., CpG oligodeoxynucleotides trigger protective and curative Th1 responses in lethal murine leishmaniasis. J Immunol. 1998 Apr 15;160(8):3627-30.	

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.